

Section 5.0  
510(k) Summary

K071428

Submitter Name: ISTO Technologies, Inc.

Submitter Address: 1155 Olivette Executive Parkway, Suite 200  
St. Louis, Missouri 63132

Contact Person: Gary Gage  
Program Director

Phone Number: 314-995-6049  
Fax Number: 314-995-6025

Date Prepared: May 22, 2007

Device Trade Name: InQu™

Device Common Name: Resorbable bone void filler

Classification Name: Filler, bone void, calcium salt compound  
Classification Number: 21 CFR 888.3045  
Product Code: MQV

Predicate Device: InQu™, ISTO Technologies, Inc., K063359

SEP 17 2007

Statement of  
Intended Use: InQu™ is a resorbable bone void filler intended to fill bony gaps or voids that are not intrinsic to the stability of the bony structure. InQu™ is intended for use as a bone graft substitute in the skeletal system (extremities and pelvis). InQu™ is indicated for use as a bone graft extender in the spine when combined with bone autograft. These defects may be surgically created or result from traumatic injury to the bone.

Device Description,  
Summary of  
Technological  
Characteristics, and  
Comparison to the  
Predicate Device InQu™ is intended for single patient use only. InQu™ is a sterile, granular, synthetic bone void filler device composed of poly (D, L-lactide-co-glycolide) and hyaluronic acid. It resorbs and is replaced with bone during the healing process. Testing has confirmed InQu™ is biocompatible, safe and effective as a general bone void filler device and as a bone graft extender in spine. InQu™ is substantially equivalent to the predicate device in terms of material composition and technological characteristics, and is in fact the same product as the unmodified predicate device, InQu™ (FDA cleared, K063359).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 17 2007

ISTO Technologies, Inc.  
% Patsy J. Trisler, J.D.,  
Regulatory Consultant  
1155 Ollivette Executive Pkwy.- Suite 200  
St. Louis, MO 63132

Re: K071428  
Trade/Device Name: InQu™  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable calcium salt bone void filler device  
Regulatory Class: Class II  
Product Code: MQV  
Dated: August 13, 2007  
Received: August 15, 2007

Dear Ms. Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K071428

Device Name: InQu™

**Indications for Use:**

InQu™ is a resorbable bone void filler intended to fill bony gaps or voids that are not intrinsic to the stability of the bony structure. InQu™ is intended for use as a bone graft substitute in the skeletal system (extremities and pelvis). InQu™ is indicated for use as a bone graft extender in the spine when combined with bone autograft. These defects may be surgically created or result from traumatic injury to the bone.

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

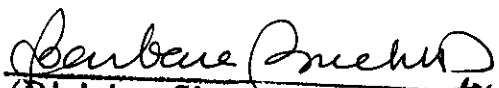
AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

  
(Division Sign-Off) *for NCM*  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K071428